February 26, 2021

Shandong Zhushi Pharmaceutical Group Co., Ltd
℅ Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
Room608, No.738,Shangcheng Rd., Pudong
Shanghai, 200120
China

Re: K203439
Trade/Device Name: Disposable Vinyl Examination Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I, reserved
Product Code: LYZ
Dated: November 5, 2020
Received: November 23, 2020

Dear Boyle Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Ryan Ortega, PhD
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203439

Device Name
Disposable Vinyl Examination Gloves

Indications for Use *(Describe)*
The Disposable Vinyl Examination Gloves are intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(K203439)

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92.

1.0 Submitter's Information

Name: Shandong Zhushi Pharmaceutical Group Co., Ltd
Address: No.6 Shande Road, Shan County, Heze City, Shandong, China
Phone Number: +86-15764021131
Contact: Junhui Zhu
Date of Preparation: 03/11/2020

Designated Submission Correspondent

Mr. Boyle Wang
Shanghai Truthful Information Technology Co., Ltd.
Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China
Tel: +86-21-50313932
Email: Info@truthful.com.cn

2.0 Device information

Trade name: Disposable Vinyl Examination Gloves
Common name: Non-powdered Patient Examination Glove
Classification name: Vinyl Patient Examination Glove
Model(s): XS, S, M, L, XL

3.0 Classification

Production code: LYZ
Regulation number: 21CFR880.6250
Classification: Class I
Panel: General Hospital

4.0 Predicate device information

Manufacturer: Hebei Hongtai Plastic Products Company Limited
Device: Vinyl Patient Examination Gloves (White, Blue, Yellow)
510(k) number: K163168

5.0 Indication for Use

The Disposable Vinyl Examination Gloves are intended for medical purposes that is worn on the examiners hands to prevent contamination between patient and examiner.

6.0 Device description

The subject device is powder free vinyl patient examination gloves. The subject device is clear, non-colored. The design of subject device is addressing the standards as ASTM D6124, ASTM D5151, and ASTM D5250. The subject device is non-sterile.

7.0 Technological Characteristics

Table1-General Comparison

Item	Subject device	Predicated device	Comparison
510(k) number	K203439	K163168	/
Product Code	LYZ	LYZ	Same
Regulation No.	21CFR880.6250	21CFR880.6250	Same
Class	I	I	Same
Intended Use	The Disposable Vinyl Examination Gloves are a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	The Vinyl Examination Glove (White, Blue, or Yellow) is a disposable device intended for medical purposes that is worn on the examiner's hands to prevent contamination between patient and examiner.	Same
Powdered or Powered free	Powdered free	Powdered free	Same
Design Feature	ambidextrous	ambidextrous	Same
Labeling Information	Single use, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Single use, powder free, device color, device name, glove size and quantity, Vinyl Examination Gloves, Non-Sterile	Similar
Sterility	Non-Sterile	Non-Sterile	Same

Table2 Device Dimensions Comparison

Predicate Device(K163168)	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	230	230	235	245	245	min
	Width, mm	80	85	95	105	115	±5
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.08					min
Subject Device	Designation	Size					Tolerance
		XS	S	M	L	XL	
	Length, mm	220	220	230	230	230	min
	Width, mm	70	80	90	100	110	±5
	Thickness, mm:						
	Finger	0.05					min
	Palm	0.08					min
Remark	SAME						

Table3 Performance Comparison

Item			Subject device	Predicated device	Comparison
Colorant			Clear, Non-Colored	White, Blue, Yellow	Analysis1
Physical Properties	Before Aging	Tensile Strength	11MPa, min	15MPa, min	Analysis2
		Ultimate Elongation	300%min	380%min	Analysis2
	After Aging	Tensile Strength	11MPa, min	15MPa, min	Analysis2
		Ultimate Elongation	300%min	380%min	Analysis2
	Comply with ASTM D5250			Comply with ASTM D5250	SAME
Freedom from Holes			Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	Be free from holes when tested in accordance with ASTM D5151 AQL=2.5	SAME
Powder Content			＜0.04 mg per glove. Meets the requirements of ASTM D6124	Meet the requirements of ASTM D6124	SIMILAR

Analysis1：The subject device (colorless) has different color to the predicate device (White, Blue, Yellow), but all proposed devices are conducted the biocompatibility test, the test results shown that the color difference do not affect the safety of proposed device.

Analysis2: The tensile strength and ultimate elongation are different with that of the predicate, but they all meet the requirements of ASTM D5250, so the differences do not raise any new safety or performance questions.

Table4 Safety Comparison

Item		Subject device	Predicated device	Comparison
Material		Vinyl	Vinyl	SAME
Biocompatibility	Irritation	Under the conditions of the study, not an irritant. Complies with ISO 10993-10	Comply with ISO10993-10	SAME
	Sensitization	Under conditions of the study, not a sensitizer. Complies with ISO 10993-10		
	Cytotoxicity	Under conditions of the study, did not show potential toxicity to L-929 cells. Complies with ISO 10993-5	/	Different
Label and Labeling		Meet FDA's Requirement	Meet FDA's Requirement	SAME

8.0 Discussion of non-clinical and clinical test performed

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards:

ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity

ASTM D6124-06 (Reapproved 2017), Standard Test Method for Residual Powder on Medical Gloves

ASTMD5151-06(Reapproved2015), Standard Test Method for Detection of Holes in Medical Gloves.

ASTM D5250-06, Standard Specification for Poly (vinyl chloride) Gloves for Medical Application.

Clinical testing is not needed for this device.

9.0 Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicated device.